

STAFF REPORT

REGULATION 11, RULE 9: AIRBORNE TOXIC CONTROL MEASURE FOR ETHYLENE OXIDE STERILIZERS

Executive Summary

Amendments to Regulation 11, Rule 9 are being proposed in order to incorporate changes made by the California Air Resources Board (CARB) to the Airborne Toxic Control Measure (ATCM) for emissions of Ethylene Oxide Sterilizers. CARB originally adopted the Ethylene Oxide Sterilizer ATCM in March 1991. In November of 1994, the United States Environmental Protection Agency (US EPA) adopted the National Emission Standard for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation operations which is somewhat different from the ATCM. The recently adopted amendments to the ATCM are expected to result in EPA approval of the ATCM as a substitute for the NESHAP. This action will enable facilities in California to be subject to only one rule, the ATCM. The proposed amendments to Regulation 11, Rule 9 will rescind the existing District rule and adopt, by reference, the State ATCM. The elimination of duplicative, overlapping rules will not affect emissions of ethylene oxide; however, it will save affected facilities the costs associated with complying with three separate, but similar rules. Affected parties have been notified and staff recommends adoption of the proposed amendments.

Background

CARB originally adopted the ATCM in March 1991 to reduce emissions of ethylene oxide from non-commercial sterilizers and aerators and commercial sterilizers and aerators using less than 2,000 pounds of ethylene oxide per 12 consecutive months. Both CARB and the Office of Environmental Health Hazard Assessment (OEHHA) determined that sufficient evidence exists to demonstrate the carcinogenicity of ethylene oxide in humans. The International Agency for Research on Cancer (IARC) concurs with this finding.

On March 7, 1994 US EPA promulgated the NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations. The requirements of the NESHAP are similar but not identical to the requirements of the original ATCM. The requirements of the NESHAP became effective on November 6, 1994. On April 7, 1999, CARB formally requested that the EPA determine that the ATCM is equivalent to the Federal NESHAP.

Equivalency is the regulatory process that US EPA uses to approve an alternative state or local rule that achieves emission reductions greater than or equal to the NESHAP. The equivalency process is set forth in a regulation promulgated under section 112(l) of the Clean Air Act and contained in 40 CFR Part 63, Subpart E.

Rather than subjecting source owners and operators to two regulations, CARB amended the original ATCM to incorporate provisions that are necessary for US EPA to approve the ATCM as an equivalent rule. At a public hearing held on May 21, 1998, CARB approved the amended ATCM for ethylene oxide emissions. The ATCM was amended in order to consolidate the State and Federal requirements for ethylene oxide sterilizer and aerator into a single regulation while maintaining the public health protections of both regulations.

CARB formally applied to the US EPA for the amended ATCM to be deemed equivalent to the NESHAP in a letter dated April 7, 1999. US EPA denied the original amended ATCM request for equivalency, and has been working with the CARB to draft a new ATCM that will incorporate delegation of authority as well as the original ATCM emissions and recordkeeping requirements. Currently, both the US EPA and CARB expect a mutually acceptable ATCM to be submitted to the US EPA for equivalency adjudication by the end of 2000. Any further changes made to the ATCM as a result of negotiations between the EPA and CARB for purposes for equivalency determinations will not affect any of the operational provisions of the ATCM.

CARB has encouraged local air districts to adopt the ATCM by reference. Adoption by reference eliminates the need for the District to apply separately to US EPA for rule equivalency.

Proposed Amendments

Requirements of the recently amended ATCM include:

- All ETO emissions from sterilizations chambers must be abated by at least 99% from each vent.
- ETO emissions from any aeration chamber exhaust are limited to a maximum concentration of 1 ppmv.
- ETO emissions from any sterilization chamber exhaust are limited to a maximum concentration of 5,300 ppmv.
- Compliance and Performance Testing: Emission limits do not apply during “upsets” as long as no additional ETO is charged to the sterilizer during the upset
- Compliance and monitoring is dependent on whether abatement is by use of an acid-water scrubber, or by catalytic oxidation (or by other method).
 1. Acid-water scrubber: baseline for abatement efficiency is determined by testing and material balance calculations. Monitoring shall be by continuous measurement of the ethylene glycol concentration in the recirculating water bath fluid.
 2. Catalytic oxidation: baseline is based on temperature change across oxidizer catalyst bed. Efficiency of the unit is determined via mass balance, and is tied to the three-hour combustion temperature in the oxidizer unit. Monitoring shall be by continuous measurement of the temperature in the catalyst bed.
 3. Other methods: for units other than acid-water scrubbers and catalytic oxidizers, the operator must provide sufficient information, including controlling operation parameters, to indicate accurate operation and maintenance of system. Monitoring shall be by agreement provided by operator and approved by Administrator.

- Ethylene oxide must be measured at the outlet of the aeration chamber on an hourly basis during operation.
- Recordkeeping: For existing facilities, report last twelve-month use of ETO within 45 days of effective date of standard, or within 45 days of exceeding the use threshold. For new operations, estimate use of ETO for the first twelve months of operation.
- Retention of information required under the General Provisions must be kept for five years.
- Any sterilization facility claiming a low-use exemption (annual usage less than 908 kg/20,000 lbs) must maintain records on a twelve-month rolling average.

Emissions and Emission Reductions

The proposed rescission of the existing District rule and adoption by reference of the State ATCM should not result in any significant changes in emission levels.

Economic Impacts

Section 40728.5 of the Health and Safety Code requires districts to assess the socioeconomic impacts of amendments to regulations that, "...will significantly affect air quality or emissions limitations." This regulatory proposal does not significantly affect air quality or emissions limitations, so the assessment is not required. However, there are positive economic impacts associated with this proposal, because of cost savings realized from affected facilities not having to comply with two separate sets of recordkeeping and reporting requirements.

Under Health and Safety Code Section 40920.6, the District is required to perform an incremental cost analysis for a proposed rule. To perform this analysis, the District must (1) identify one or more control options achieving the emission reduction objectives for the proposed rule, (2) determine the cost effectiveness for each option, and (3) calculate the incremental cost effectiveness for each option. As stated above, there are no quantifiable emission reductions associated with rescission of the existing District rule and adoption of the amended State ATCM.

Environmental Impacts

The District has determined that these amendments to Regulation 11, Rule 9 are exempt from provisions of the California Environmental Quality Act (CEQA) pursuant to State CEQA Guidelines, Section 15061, subd. (b)(3), and Section 15321. The proposed amendments will not result in any more or any less emissions from ethylene oxide sterilization and aeration operations within the District. Consequently, these proposed amendments have no potential for adverse environmental impacts and are exempt under Guidelines Section 15061, subd (b)(3). The District intends to file a Notice of Exemption pursuant to State CEQA Guidelines, Section 15062.

Regulatory Impacts

Section 40727.2 of the Health and Safety Code requires a district to identify existing federal and district air pollution control requirements for the equipment or source type affected by the proposed change in district rules. The district must then note any differences between these existing requirements and the requirements imposed by the proposed change. Where the district proposal does not impose a new standard, make an existing standard more stringent, or impose new or more stringent administrative requirements, the district may simply note this fact without further analysis.

The NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations promulgated in November 1994 contains similar requirements to the amended ATCM. When the amended ATCM is approved as an equivalent rule by US EPA, then the NESHAP will not apply to affected facilities. Thus there are no separate federal rules that affects these sources.

Conclusion

The proposed amendments would rescind the existing BAAQMD Regulation 11, Rule 9, and adopt by reference the current ATCM. This action will consolidate State and Federal requirements for affected facilities into a single rule. Adoption of these amendments will not impose any new standards on affected industry, nor will it result in any adverse economic impacts. No significant impact is expected on District staff resources. A workshop was held on _____ to discuss the NESHAP and proposed District adoption of the amended ATCM.

Pursuant to the California Health and Safety Code, Section 40727, regulatory amendments must meet findings of necessity, authority, clarity, consistency, non-duplication, and reference. The proposed amendments are:

Necessary for the District to implement and enforce State and Federal standards;

Authorized by the California Health and Safety Code Section 40702;

Clear, in that the amendments adopt by reference the provisions of Sections 93108 and 93108.5, Title 17 of the California Code of Regulations;

Consistent with other District rules, and not in conflict with any State or Federal law;

Non-duplicative of other statutes, rules or regulation; and

Written to provide the proper references to the applicable State regulation.

The proposed amendments to Regulation 11, Rule 9 have met all legal notice requirements. Staff will recommend adoption of the proposed amendments.

The State ATCM is attached to this report as Appendix A.

CSF:csf